

108TH CONGRESS
2D SESSION

H. R. 4790

To amend the Federal Food, Drug, and Cosmetic Act to authorize the importation of prescription drugs from Canada and certain other countries, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 9, 2004

Mr. JOHN introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to authorize the importation of prescription drugs from Canada and certain other countries, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Drug Importation Promotion and Safety Act”.

6 (b) TABLE OF CONTENTS.—The table of contents for
7 this Act is as follows:

Sec. 1. Short title; table of contents.

Sec. 2. Importation of prescription drugs; Office of Drug Importation Promotion and Safety; other general provisions.

- Sec. 3. Commercial importation.
- Sec. 4. Personal importation; Internet pharmacies.
- Sec. 5. Personal importation; entering United States in possession of prescription drugs; compassionate use.
- Sec. 6. Particular products; suspension of authority for importation.
- Sec. 7. Registration of importation facilities.
- Sec. 8. Enforcement; regulations; effective dates.
- Sec. 9. Licensing of Internet pharmacies.
- Sec. 10. Chain of custody of prescription drugs; network for notifications regarding counterfeit drugs.

1 **SEC. 2. IMPORTATION OF PRESCRIPTION DRUGS; OFFICE**
 2 **OF DRUG IMPORTATION PROMOTION AND**
 3 **SAFETY; OTHER GENERAL PROVISIONS.**

4 Chapter VIII of the Federal Food, Drug, and Cos-
 5 metic Act (21 U.S.C. 381 et seq.) is amended—

6 (1) by inserting after the chapter heading the
 7 following:

8 **“Subchapter A—General Provisions”**; and

9 (2) by adding at the end the following:

10 **“Subchapter B—Importation of Prescription**
 11 **Drugs**

12 **“SEC. 811. GENERAL PROVISIONS.**

13 “(a) OFFICE OF DRUG IMPORTATION PROMOTION
 14 AND SAFETY.—There is established within the Office of
 15 the Commissioner of Food and Drugs an office to be
 16 known as the Office of Drug Importation Promotion and
 17 Safety, which shall be headed by an Associate Commis-
 18 sioner appointed by the Commissioner. The Commissioner
 19 of Food and Drugs shall carry out this subchapter acting
 20 through such Associate Commissioner.

1 “(b) ANNUAL REPORT.—The Secretary shall annu-
2 ally submit to the Congress a report on activities carried
3 out under this subchapter, including a determination by
4 the Secretary of whether prescription drugs imported
5 under this subchapter are safe and effective.

6 “(c) DEFINITIONS.—For purposes of this subchapter:

7 “(1) DRUG IMPORTATION FACILITY.—The term
8 ‘drug importation facility’ means a person, other
9 than an individual importing a prescription drug
10 under section 814, located outside the United States
11 (other than a transporter) that engages in the dis-
12 tribution or dispensing of a prescription drug that is
13 imported or offered for importation into the United
14 States.

15 “(2) INTERNET PHARMACY.—The term ‘Inter-
16 net pharmacy’ means a person, other than an indi-
17 vidual importing a prescription drug under section
18 814, that offers to dispense in the United States a
19 prescription drug through an Internet website in
20 interstate commerce, regardless of whether the phys-
21 ical location of the principal place of business of the
22 Internet pharmacy is in the United States or in an-
23 other country.

24 “(3) PHARMACY.—The term ‘pharmacy’ means
25 a person, other than an individual importing a pre-

1 scription drug under section 814, licensed by a State
2 to dispense prescription drugs or to provide pharma-
3 ceutical care.

4 “(4) PERMITTED COUNTRY.—The term ‘per-
5 mitted country’ means—

6 “(A) Australia;

7 “(B) a member country of the European
8 Union as of January 1, 2003;

9 “(C) Japan;

10 “(D) New Zealand;

11 “(E) Switzerland; and

12 “(F) such additional countries as the Sec-
13 retary may specify.

14 “(5) PRESCRIPTION DRUG.—

15 “(A) IN GENERAL.—The term ‘prescription
16 drug’ means a drug described in section 503(b)
17 that is approved by the Secretary under section
18 505.

19 “(B) EXCLUSIONS.—The term ‘prescrip-
20 tion drug’ does not include—

21 “(i) a controlled substance (as defined
22 in section 102 of the Controlled Sub-
23 stances Act (21 U.S.C. 802));

1 “(ii) a biological product (as defined
2 in section 351 of the Public Health Service
3 Act (42 U.S.C. 262));

4 “(iii) an infused drug (including a
5 peritoneal dialysis solution);

6 “(iv) an intravenously injected drug;

7 “(v) a drug that is inhaled during sur-
8 gery;

9 “(vi) a parenteral drug;

10 “(vii) a drug manufactured through 1
11 or more biotechnology processes, includ-
12 ing—

13 “(I) a therapeutic DNA plasmid
14 product;

15 “(II) a therapeutic synthetic
16 peptide product of not more than 40
17 amino acids;

18 “(III) a monoclonal antibody
19 product for in vivo use; and

20 “(IV) a therapeutic recombinant
21 DNA-derived product;

22 “(viii) a drug required to be refrig-
23 erated at any time during manufacturing,
24 packing, processing, or holding; or

25 “(ix) a photoreactive drug.

1 “(6) TREATING PROVIDER.—The term ‘treating
2 provider’ means a licensed health care provider
3 that—

4 “(A)(i) performs a documented patient
5 evaluation (including a patient history and
6 physical examination) of an individual to estab-
7 lish the diagnosis for which a prescription drug
8 is prescribed;

9 “(ii) discusses with the individual the
10 treatment options of the individual and the
11 risks and benefits of treatment; and

12 “(iii) maintains contemporaneous medical
13 records concerning the individual; or

14 “(B) provides care to an individual as part
15 of an on-call or cross-coverage arrangement
16 with a health care provider described in sub-
17 paragraph (A).

18 “(7) WHOLESALER.—

19 “(A) IN GENERAL.—The term ‘wholesaler’
20 means a person licensed as a wholesaler or dis-
21 tributor of prescription drugs in the United
22 States as described in section 503(e)(2).

23 “(B) EXCLUSION.—The term ‘wholesaler’
24 does not include—

1 “(i) a person authorized to import
2 drugs under section 801(d)(1); or

3 “(ii) an individual importing a pre-
4 scription drug under section 812.”.

5 **SEC. 3. COMMERCIAL IMPORTATION.**

6 Subchapter B of chapter VIII of the Federal Food,
7 Drug, and Cosmetic Act, as added by section 2 of this
8 Act, is amended by adding at the end the following section:

9 **“SEC. 812. COMMERCIAL IMPORTATION.**

10 **“(a) IN GENERAL.—**

11 **“(1) NO PRESUMPTION AGAINST IMPORTA-**
12 **TION.—**A drug importation facility, pharmacy, Inter-
13 net pharmacy, or wholesaler may import a prescrip-
14 tion drug from Canada or a permitted country into
15 the United States for dispensing in the United
16 States unless the importation of the prescription
17 drug is not in accordance with this subchapter.

18 **“(2) LIMITATION TO CERTAIN PORTS.—**The
19 Secretary may limit the ports of entry in the United
20 States through which a prescription drug may be
21 imported under this section to a reasonable number
22 of ports designated by the Secretary.

23 **“(b) REQUIREMENTS.—**Each prescription drug im-
24 ported under this subchapter shall—

25 **“(1)** be approved under section 505;

1 “(2) comply with sections 501 and 502;

2 “(3) be in a container that bears a label stat-
3 ing, in prominent and conspicuous type—

4 “(A) the lot number of the prescription
5 drug;

6 “(B) the name, address and phone number
7 of the drug importation facility;

8 “(C) comply with regulations promulgated
9 by the Secretary to require labeling regarding
10 the fact that the drug is imported; and

11 “(D) a unique identifier code provided by
12 the Secretary that modifies the national drug
13 code of the prescription drug to indicate that
14 the drug has been imported; and

15 “(4) comply with any other applicable require-
16 ment of this Act.

17 “(c) APPROVED LABELING.—

18 “(1) IN GENERAL.—A drug importation facility
19 that offers for importation a prescription drug under
20 this subchapter shall submit to the Secretary an ap-
21 plication for approval that demonstrates that the la-
22 beling of the prescription drug to be imported into
23 the United States complies with the requirements of
24 sections 502 and 503.

1 “(2) PROCEDURE.—Not later than 60 days
2 after receipt of a completed application under para-
3 graph (1), the Secretary shall—

4 “(A) approve or deny the application con-
5 sistent with the requirements of sections 502
6 and 503; and

7 “(B) notify the applicant of the decision of
8 the Secretary and, if the application is denied,
9 the reason for the denial.

10 “(3) LISTS.—

11 “(A) APPLICATIONS.—The Secretary shall
12 maintain an updated list of applications pend-
13 ing, applications approved, and applications de-
14 nied under this subsection.

15 “(B) PORTS.—The Secretary shall main-
16 tain an updated list of ports through which a
17 prescription drug may be imported under this
18 section and make the list available to the public
19 on an Internet website.

20 “(d) PROHIBITION OF IMPORTATION OF A PRESCRIP-
21 TION DRUG THAT ENTERS OTHER COUNTRIES.—

22 “(1) IN GENERAL.—A drug importation facility,
23 pharmacy, Internet pharmacy, or wholesaler shall
24 not import a prescription drug if, during any period
25 in which the prescription drug was not in the control

1 of the manufacturer, the prescription drug entered a
2 country other than—

3 “(A) Canada; or

4 “(B) subject to paragraph (2), a permitted
5 country.

6 “(2) LIMITATION.—The Secretary may exclude
7 one or more of the countries under subparagraph
8 (B) of paragraph (1) from the application of that
9 subparagraph if the Secretary determines that allow-
10 ing a prescription drug to be imported into the
11 United States after having entered that country out-
12 side control of a manufacturer would present a risk
13 to the public health.

14 “(e) PROHIBITION OF COMMINGLING.—

15 “(1) IN GENERAL.—A drug importation facility,
16 pharmacy, Internet pharmacy, or wholesaler shall
17 not commingle a prescription drug imported into the
18 United States under this subchapter with a prescrip-
19 tion drug that is not imported from Canada or a
20 permitted country.

21 “(2) LABEL.—A pharmacy or Internet phar-
22 macy that dispenses a prescription drug imported
23 from Canada or a permitted country shall affix on
24 each dispensed container of the prescription drug

1 the label required under subsection (b)(3) unless
2 such a label is already affixed to the container.

3 “(f) DRUG RECALLS.—On receipt of notification
4 from the manufacturer of a prescription drug imported
5 from Canada or a permitted country under this section
6 that the prescription drug has been recalled or withdrawn
7 from the market in Canada or a permitted country, a drug
8 importation facility shall promptly provide the Secretary
9 and any person to whom the prescription drug was distrib-
10 uted a notice that the drug has been recalled or withdrawn
11 from the market and that includes—

12 “(1) information (including the lot number)
13 that identifies the prescription drug; and

14 “(2) a statement of the reason for the recall or
15 withdrawal.

16 “(g) CHARITABLE CONTRIBUTIONS.—Notwith-
17 standing any other provision of this section, section
18 801(d)(1) continues to apply to a prescription drug that
19 is donated or otherwise supplied at no charge or a nominal
20 charge by the manufacturer of the prescription drug to
21 a charitable or humanitarian organization (including the
22 United Nations and affiliates) or to a government of a
23 foreign country.

24 “(h) JURISDICTION.—The district courts of the
25 United States shall have jurisdiction in an action brought

1 by the United States against a person importing or offer-
 2 ing for importation a prescription drug in violation of the
 3 requirements of this section.

4 “(i) EFFECT OF SECTION.—Nothing in this section
 5 limits the authority of the Secretary relating to the impor-
 6 tation of prescription drugs (including the interdiction of
 7 prescription drugs that are unapproved, adulterated, or
 8 misbranded), other than with respect to section 801(d)(1)
 9 as provided in subsection (g).”.

10 **SEC. 4. PERSONAL IMPORTATION; INTERNET PHARMACIES.**

11 Subchapter B of chapter VIII of the Federal Food,
 12 Drug, and Cosmetic Act, as amended by section 3 of this
 13 Act, is amended by adding at the end the following section:

14 **“SEC. 813. PERSONAL IMPORTATION; INTERNET PHAR-**
 15 **MACIES.**

16 “An individual may, for personal use or for the use
 17 of a family member of the individual (rather than for re-
 18 sale), import a prescription drug into the United States
 19 from any Internet pharmacy that is registered under sec-
 20 tion 816 and licensed under section 503B, except to the
 21 extent that the Secretary determines that importation of
 22 the prescription drug is not in accordance with this sub-
 23 chapter.”.

1 **SEC. 5. PERSONAL IMPORTATION; ENTERING UNITED**
2 **STATES IN POSSESSION OF PRESCRIPTION**
3 **DRUGS; COMPASSIONATE USE.**

4 Subchapter B of chapter VIII of the Federal Food,
5 Drug, and Cosmetic Act, as amended by section 4 of this
6 Act, is amended by adding at the end the following section:

7 **“SEC. 814. PERSONAL IMPORTATION; ENTERING UNITED**
8 **STATES IN POSSESSION OF PRESCRIPTION**
9 **DRUGS; COMPASSIONATE USE.**

10 “(a) IN GENERAL.—An individual may, for personal
11 use or for the use of a family member of the individual
12 (rather than for resale), import a prescription drug from
13 Canada or a permitted country into the United States,
14 subject to subsections (b) and (c).

15 “(b) IMPORTATION.—An individual may import a
16 prescription drug if—

17 “(1) the prescription drug is purchased from a
18 licensed pharmacy in Canada or a licensed pharmacy
19 in a permitted country and dispensed in compliance
20 with the applicable laws of Canada or the permitted
21 country regarding the practice of pharmacy;

22 “(2) the prescription drug is imported from
23 Canada or a permitted country into the United
24 States;

25 “(3) the prescription drug is imported by the
26 individual on the person of the individual;

1 “(4) the quantity of the prescription drug im-
 2 ported does not exceed a 90-day supply during any
 3 90-day period; and

4 “(5) the prescription drug is accompanied by—

5 “(A) a copy of a prescription valid in a
 6 State and cosigned by a prescribing physician
 7 in Canada or the permitted country; or

8 “(B) if the prescription drug is available in
 9 Canada or the permitted country without a pre-
 10 scription, a copy of the valid prescription signed
 11 by a pharmacist licensed in Canada or the per-
 12 mitted country.

13 “(c) COMPASSIONATE USE.—The Secretary may per-
 14 mit an individual to import an up to a 90-day supply of
 15 a drug that is not approved by the Secretary under section
 16 505 if the importation is for continuation of personal use
 17 by the individual for treatment, begun in a foreign coun-
 18 try, of a serious medical condition.”.

19 **SEC. 6. PARTICULAR PRODUCTS; SUSPENSION OF AUTHOR-**
 20 **ITY FOR IMPORTATION.**

21 Subchapter B of chapter VIII of the Federal Food,
 22 Drug, and Cosmetic Act, as amended by section 5 of this
 23 Act, is amended by adding at the end the following section:

1 **“SEC. 815. PARTICULAR PRODUCTS; SUSPENSION OF AU-**
2 **THORITY FOR IMPORTATION.**

3 “(a) **PRESCRIPTION DRUG.**—If the Secretary deter-
4 mines that the importation of a particular prescription
5 drug or particular dosage form of a prescription drug into
6 the United States presents a risk to the public health, the
7 Secretary may immediately order the suspension of the
8 importation of the particular prescription drug or par-
9 ticular dosage form of the prescription drug.

10 “(b) **SUSPENSION.**—If the Secretary determines that
11 a drug importation facility, pharmacy, Internet pharmacy,
12 or wholesaler is engaged in a pattern of importing or offer-
13 ing for importation a prescription drug into the United
14 States in violation of any of the requirements of this Act,
15 the Secretary may immediately order the suspension of
16 that person from engaging in the importation or offering
17 for importation of prescription drugs into the United
18 States.

19 “(c) **CANADA OR PERMITTED COUNTRY.**—If the Sec-
20 retary determines that there is a pattern of prescription
21 drugs being imported or offered for importation into the
22 United States from Canada or a permitted country in vio-
23 lation of any of the requirements of this Act, the Secretary
24 may immediately order the suspension of the importation
25 or offering for importation into the United States of pre-

1 scription drugs from Canada or that permitted country,
2 as appropriate.

3 “(d) APPEAL OF SUSPENSION ORDER.—

4 “(1) IN GENERAL.—

5 “(A) PRESCRIPTION DRUGS.—With respect
6 to the importation of a prescription drug, the
7 importation of which is suspended under sub-
8 section (a), any person that would be entitled to
9 be a claimant for the prescription drug may ap-
10 peal the suspension order to the Secretary.

11 “(B) SUSPENDED PERSONS.—With respect
12 to a drug importation facility, pharmacy, Inter-
13 net pharmacy, or wholesaler subject to a sus-
14 pension order under subsection (b) or (c), the
15 drug importation facility, pharmacy, Internet
16 pharmacy or wholesaler may appeal the suspen-
17 sion order to the Secretary.

18 “(2) ACTION BY THE SECRETARY.—Not later
19 than 30 days after an appeal is filed, the Secretary,
20 after providing opportunity for an informal hearing,
21 shall confirm or terminate the order.

22 “(3) FAILURE TO ACT.—If, during the 30-day
23 period specified in paragraph (2), the Secretary fails
24 to provide an opportunity for a hearing or to con-

1 firm or terminate the order, the order shall be
2 deemed to be terminated.

3 “(e) NO JUDICIAL REVIEW.—An order under this
4 section shall not be subject to judicial review.

5 “(f) EFFECT OF SECTION.—Nothing in this section
6 applies to a prescription drug imported by an individual
7 under section 812 or to a commercial transaction con-
8 ducted between an Internet pharmacy and an individual.”.

9 **SEC. 7. REGISTRATION OF IMPORTATION FACILITIES.**

10 (a) IN GENERAL.—Subchapter B of chapter VIII of
11 the Federal Food, Drug, and Cosmetic Act, as amended
12 by section 6 of this Act, is amended by adding after sec-
13 tion 815 the following section:

14 **“SEC. 816. REGISTRATION OF CERTAIN IMPORTERS.**

15 “(a) IN GENERAL.—A drug importation facility,
16 pharmacy, Internet pharmacy, or wholesaler engaged in
17 the importation or offering for importation of prescription
18 drugs into the United States, or in the dispensing of such
19 drugs, shall register with the Secretary in accordance with
20 this section.

21 “(b) REGISTRATION.—

22 “(1) IN GENERAL.—To register, the owner, op-
23 erator, or agent in charge of a drug importation fa-
24 cility, pharmacy, Internet pharmacy, or wholesaler

1 shall submit to the Secretary a registration that dis-
2 closes—

3 “(A) the name and address of each drug
4 importation facility, pharmacy, Internet phar-
5 macy, or wholesaler at which, and all trade
6 names under which, the registrant conducts
7 business;

8 “(B) the name of each prescription drug to
9 be imported into the United States by each
10 drug importation facility, pharmacy, Internet
11 pharmacy, or wholesaler; and

12 “(C) the name and address of an agent for
13 service of process in the United States.

14 “(2) CHANGE IN INFORMATION.—The reg-
15 istrant shall notify the Secretary in a timely manner
16 of any change in the information provided under
17 paragraph (1).

18 “(3) PROCEDURE.—Not later than 60 days
19 after receipt of a completed registration under para-
20 graph (1), the Secretary shall—

21 “(A) assign a registration number to each
22 registered drug importation facility, pharmacy,
23 Internet pharmacy, and wholesaler; and

24 “(B) notify the registrant of the receipt of
25 the registration.

1 “(4) LIST.—

2 “(A) IN GENERAL.—The Secretary shall
3 compile, maintain, and periodically update a list
4 of registrants.

5 “(B) AVAILABILITY.—The Secretary shall
6 make the list described under subparagraph (A)
7 and information submitted by a registrant
8 under paragraph (1) available to the public on
9 an Internet website and through a toll-free tele-
10 phone number.

11 “(c) ELECTRONIC FILING.—

12 “(1) IN GENERAL.—For the purpose of reduc-
13 ing paperwork and reporting burdens, the Secretary
14 shall provide for, and require the use of, electronic
15 methods of submitting to the Secretary registrations
16 required under this section and shall provide for
17 electronic methods of receiving the registrations.

18 “(2) AUTHENTICATION.—In providing for the
19 electronic submission of such registrations under
20 this section, the Secretary shall ensure that ade-
21 quate authentication protocols are used to allow
22 identification of the registrant and validation of the
23 data as appropriate.

24 “(d) EFFECT OF SECTION.—

1 “(1) AUTHORITY.—Nothing in this section au-
2 thorizes the Secretary to require an application, re-
3 view, or licensing process for a drug importation fa-
4 cility, pharmacy, or wholesaler.

5 “(2) IMPORTATION BY INDIVIDUALS.—Nothing
6 in this section applies to a prescription drug im-
7 ported by an individual under section 814 or to a
8 commercial transaction conducted between an Inter-
9 net pharmacy and an individual.”.

10 (b) IMPORTATION; FAILURE TO REGISTER.—Section
11 801 of the Federal Food, Drug, and Cosmetic Act is
12 amended by adding at the end the following:

13 “(p) FAILURE TO REGISTER.—

14 “(1) IN GENERAL.—If a drug importation facil-
15 ity, pharmacy, Internet pharmacy, or wholesaler en-
16 gaged in the importation or offering for importation
17 of prescription drugs into the United States has not
18 submitted a registration to the Secretary in accord-
19 ance with section 816, a prescription drug that is
20 being imported or offered for importation into the
21 United States shall not be delivered to the importer,
22 owner, or consignee of the prescription drug until
23 the drug importation facility, pharmacy, Internet
24 pharmacy, or wholesaler is registered in accordance
25 with section 816.

1 “(2) EFFECT OF SUBSECTION (B).—Subsection
2 (b) does not authorize the delivery of the prescrip-
3 tion drug pursuant to the execution of a bond while
4 the prescription drug is held under this subsection.

5 “(3) REMOVAL.—A prescription drug held
6 under this subsection shall be removed to a secure
7 facility, as appropriate.

8 “(4) NO TRANSFER.—During the period in
9 which a prescription drug is held under this sub-
10 section, the prescription drug shall not be trans-
11 ferred by any person from the port of entry into the
12 United States for the prescription drug or from the
13 secure facility to which the prescription drug has
14 been removed.”.

15 **SEC. 8. ENFORCEMENT; REGULATIONS; EFFECTIVE DATES.**

16 (a) PROHIBITED ACTS.—Section 301 of the Federal
17 Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amend-
18 ed by adding at the end the following:

19 “(hh) Dispensing or offering to dispense a prescrip-
20 tion drug imported into the United States in violation of
21 the requirements of section 812.

22 “(ii) The importation or offering for importation of
23 a prescription drug in violation of an order under section
24 815.

1 “(jj) The failure of a drug importation facility, phar-
2 macy, Internet pharmacy, or wholesaler engaged in the
3 importation or offering for importation of prescription
4 drugs into the United States, or in the dispensing of such
5 drugs, to register in accordance with section 816. ”.

6 (b) REGULATIONS; EFFECTIVE DATES.—

7 (1) COMMERCIAL IMPORTATION.—With respect
8 to carrying out section 812 of the Federal Food,
9 Drug, and Cosmetic Act (as added by section 3 of
10 this Act):

11 (A) The Secretary of Health and Human
12 Services (referred to in this subsection as the
13 “Secretary”) shall promulgate interim final reg-
14 ulations regarding importation of prescription
15 drugs from Canada not later than 30 days after
16 the date of the enactment of this Act. Such sec-
17 tion 812 takes effect regarding the importation
18 of prescription drugs from Canada upon the ex-
19 piration of such 30 days, without regard to
20 whether the Secretary has promulgated such
21 regulations.

22 (B) The Secretary shall promulgate in-
23 terim final regulations regarding importation of
24 prescription drugs from permitted countries not
25 later than one year after the date of the enact-

1 ment of this Act. Such section 812 takes effect
2 regarding importation of prescription drugs
3 from permitted countries upon the expiration of
4 such one-year period, without regard to whether
5 the Secretary has promulgated such regula-
6 tions.

7 (2) PERSONAL IMPORTATION; ENTERING
8 UNITED STATES IN POSSESSION OF PRESCRIPTION
9 DRUG; COMPASSIONATE USE.—The Secretary may
10 promulgate regulations to carry out section 814 of
11 the Federal Food, Drug, and Cosmetic Act (as
12 added by section 5 of this Act). Such section 813
13 takes effect upon the date of enactment of this Act,
14 without regard to whether the Secretary has promul-
15 gated such regulations.

16 (3) REGISTRATION OF IMPORTATION FACILI-
17 TIES.—Not later than one year after the date of the
18 enactment of this Act, the Secretary shall promul-
19 gate regulations to carry out section 816 of the Fed-
20 eral Food, Drug, and Cosmetic Act (as added by
21 section 7(a) of this Act). The requirement of reg-
22 istration under such section takes effect—

23 (A) on the effective date of such final regu-
24 lations; or

1 (B) if the final regulations have not been
 2 made effective as of the expiration of such one-
 3 year period, on the date that is one year after
 4 the date of the enactment of this Act, subject
 5 to compliance with the final regulations when
 6 the final regulations are made effective.

7 **SEC. 9. LICENSING OF INTERNET PHARMACIES.**

8 (a) IN GENERAL.—Chapter V of the Federal Food,
 9 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-
 10 ed by inserting after section 503A the following section:

11 **“SEC. 503B. LICENSING OF INTERNET PHARMACIES.**

12 “(a) IN GENERAL.—An Internet pharmacy that is li-
 13 censed in accordance with this section may dispense or
 14 offer to dispense a prescription drug to a person in the
 15 United States. An Internet pharmacy may not dispense
 16 or offer to dispense a prescription drug to such a person
 17 prior to obtaining a license under this section.

18 “(b) DEFINITIONS.—For purposes of this section:

19 “(1) ADVERTISING SERVICE PROVIDER.—The
 20 term ‘advertising service provider’ means an adver-
 21 tising company that contracts with a provider of an
 22 interactive computer service (as defined in section
 23 230(f) of the Communications Act of 1934 (47
 24 U.S.C. 230(f)) to provide advertising on the Inter-
 25 net.

1 “(2) PERMITTED COUNTRY.—The term ‘per-
2 mitted country’ has the meaning given such term in
3 section 811(c).

4 “(3) PRESCRIPTION DRUG.—The term ‘pre-
5 scription drug’ means a drug described in section
6 503(b) that is approved by the Secretary under sec-
7 tion 505.

8 “(4) INTERNET PHARMACY.—The term ‘Inter-
9 net pharmacy’ means a person that dispenses or of-
10 fers to dispense a prescription drug through an
11 Internet website in interstate commerce in the
12 United States regardless of whether the physical lo-
13 cation of the principal place of business of the Inter-
14 net pharmacy is in the United States or in another
15 country.

16 “(c) LICENSING OF INTERNET PHARMACIES.—

17 “(1) IN GENERAL.—The Secretary may issue a
18 license under this section to an Internet pharmacy
19 only if such pharmacy—

20 “(A) has its principal place of business in
21 the United States, Canada, or a permitted
22 country; and

23 “(B) meets the requirements of paragraph
24 (2).

25 “(2) CONDITIONS FOR LICENSING.—

1 “(A) APPLICATION REQUIREMENTS.—An
2 Internet pharmacy shall submit to the Sec-
3 retary an application for a license under this
4 section that includes—

5 “(i)(I) in the case of an Internet
6 pharmacy located in the United States,
7 verification that, in each State in which
8 the Internet pharmacy engages in dis-
9 pensing or offering to dispense prescription
10 drugs, the Internet pharmacy, and all em-
11 ployees and agents of the Internet phar-
12 macy, is in compliance with applicable
13 Federal and State laws regarding—

14 “(aa) the practice of pharmacy,
15 including licensing laws and inspec-
16 tion requirements; and

17 “(bb) the manufacturing and dis-
18 tribution of controlled substances, in-
19 cluding with respect to mailing or
20 shipping controlled substances to con-
21 sumers; or

22 “(II) in the case of an Internet phar-
23 macy located in Canada or a permitted
24 country, verification that—

1 “(aa) all employees and agents of
2 the Internet pharmacy are in compli-
3 ance with applicable laws of Canada
4 or the permitted country regarding
5 the practice of pharmacy, including li-
6 censing laws and inspection require-
7 ments; and

8 “(bb) the Internet pharmacy is in
9 compliance with applicable Federal
10 and State laws regarding the practice
11 of pharmacy, including licensing laws
12 and inspection requirements;

13 “(ii) verification that the person that
14 owns the Internet pharmacy has not had a
15 license for an Internet pharmacy termi-
16 nated by the Secretary, and that no other
17 Internet pharmacy owned by the person
18 has had a license under this subsection
19 that has been terminated by the Secretary;

20 “(iii) verification from the person that
21 owns the Internet pharmacy that the per-
22 son will permit inspection of the facilities
23 and business practices of the Internet
24 pharmacy by the Secretary to the extent
25 necessary to determine whether the Inter-

1 net pharmacy is in compliance with this
2 subsection; and

3 “(iv) in the case of an agreement be-
4 tween a patient and an Internet pharmacy
5 that releases the Internet pharmacy, and
6 any employee or agent of the Internet
7 pharmacy, from liability for damages aris-
8 ing out of the negligence of the Internet
9 pharmacy, an assurance that such a limita-
10 tion of liability shall be null and void.

11 “(B) IDENTIFICATION REQUIREMENTS.—

12 An Internet pharmacy shall provide to any per-
13 son that accesses the Internet pharmacy
14 website, on each page of the website of the
15 Internet pharmacy or by a link to a separate
16 page, the following information:

17 “(i) The street address, city, ZIP
18 Code or comparable mail code, State (or
19 comparable entity), country, and telephone
20 number of—

21 “(I) each place of business of the
22 Internet pharmacy; and

23 “(II) the name of the supervising
24 pharmacist of the Internet pharmacy
25 and each individual who serves as a

1 pharmacist for purposes of the Inter-
2 net pharmacy website.

3 “(ii) The names of all States or coun-
4 tries, as appropriate, in which the Internet
5 pharmacy and the pharmacists employed
6 by the Internet pharmacy are licensed or
7 otherwise authorized to dispense prescrip-
8 tion drugs.

9 “(iii) If the Internet pharmacy makes
10 referrals to, or solicits on behalf of, a
11 health care practitioner or group of practi-
12 tioners in the United States for prescrip-
13 tion services—

14 “(I) the name, street address,
15 city, ZIP Code or comparable mail
16 code, State, and telephone number of
17 the practitioner or group; and

18 “(II) the name of each State in
19 which each practitioner is licensed or
20 otherwise authorized to prescribe
21 drugs.

22 “(iv) A statement that the Internet
23 pharmacy will dispense prescription drugs
24 only after receipt of a valid prescription.

1 “(C) PROFESSIONAL SERVICES REQUIRE-
2 MENTS.—An Internet pharmacy shall carry out
3 the following:

4 “(i) Maintain patient medication pro-
5 files and other related data in a readily ac-
6 cessible format organized to facilitate con-
7 sultation with treating providers, care-
8 givers, and patients.

9 “(ii) Conduct prospective drug use re-
10 views before dispensing medications or
11 medical devices.

12 “(iii) Ensure patient confidentiality
13 and the protection of patient identity and
14 patient-specific information, in accordance
15 with the regulations promulgated under
16 section 264(c) of the Health Insurance
17 Portability and Accountability Act of 1996
18 (42 U.S.C. 1320d–2 note).

19 “(iv) Offer interactive and meaningful
20 consultation by a licensed pharmacist to
21 the caregiver or patient prior to and subse-
22 quent to the time at which the Internet
23 pharmacy dispenses the drug.

1 “(v)(I) Establish a mechanism for pa-
2 tients to report errors and suspected ad-
3 verse drug reactions.

4 “(II) Document in the reporting
5 mechanism the response of the Internet
6 pharmacy to those reports.

7 “(vi) Develop a system to inform care-
8 givers and patients about drug recalls.

9 “(vii) Educate caregivers and patients
10 about the appropriate means of disposing
11 of expired, damaged, or unusable medica-
12 tions.

13 “(viii) Assure that the sale of a pre-
14 scription drug is in accordance with a pre-
15 scription from the treating provider of the
16 individual.

17 “(ix)(I) Verify the validity of the pre-
18 scription of an individual by using 1 of the
19 following methods:

20 “(aa) Receiving from the indi-
21 vidual or treating provider of the indi-
22 vidual the prescription of the indi-
23 vidual by mail (including a private
24 carrier), or receiving from the treating
25 provider of the individual the prescrip-

1 tion of the individual by electronic
2 mail.

3 “(bb) If the prescription is for a
4 controlled substance (as defined in
5 section 102 of the Controlled Sub-
6 stances Act (21 U.S.C. 802)), con-
7 firming with the treating provider the
8 information in subclause (II).

9 “(II) When seeking verification of a
10 prescription of an individual under sub-
11 clause (I)(bb), an Internet pharmacy shall
12 provide to the treating provider the fol-
13 lowing information:

14 “(aa) The full name and address
15 of the individual.

16 “(bb) Identification of the pre-
17 scription drug.

18 “(cc) The quantity of the pre-
19 scription drug to be dispensed.

20 “(dd) The date on which the in-
21 dividual presented the prescription to
22 the Internet pharmacy.

23 “(ee) The date and time of the
24 verification request.

1 “(ff) The name of a contact per-
2 son at the Internet pharmacy, includ-
3 ing a voice telephone number, elec-
4 tronic mail address, and facsimile tele-
5 phone number.

6 “(III) A prescription is verified under
7 subclause (I)(bb) only if 1 of the following
8 occurs:

9 “(aa) The treating provider con-
10 firms, by direct communication with
11 the Internet pharmacy, that the pre-
12 scription is accurate.

13 “(bb) The treating provider in-
14 forms the Internet pharmacy that the
15 prescription is inaccurate and provides
16 the accurate prescription.

17 “(IV) An Internet pharmacy shall not
18 fill a prescription if—

19 “(aa) a treating provider informs
20 the Internet pharmacy within 72
21 hours after receipt of a communica-
22 tion under subclause (I)(bb) that the
23 prescription is inaccurate or expired;
24 or

1 “(bb) the treating provider does
2 not respond within that time.

3 “(x) Maintain, for such period of time
4 as the Secretary shall prescribe by regula-
5 tion, a record of all direct communications
6 with a treating provider regarding the dis-
7 pensing of a prescription drug, including
8 verification of the prescription.

9 “(3) LICENSURE PROCEDURE.—

10 “(A) ACTION BY SECRETARY.—On receipt
11 of a completed licensing application under para-
12 graph (2), the Secretary shall—

13 “(i) assign an identification number
14 to each Internet pharmacy;

15 “(ii) notify the applicant of the receipt
16 of the licensure application; and

17 “(iii) not later than 60 days after re-
18 ceipt of the licensure application, issue a li-
19 cense if the Internet pharmacy is in com-
20 pliance with conditions under paragraph
21 (3).

22 “(B) ELECTRONIC FILING.—

23 “(i) IN GENERAL.—For the purpose
24 of reducing paperwork and reporting bur-
25 dens, the Secretary shall require the use of

1 electronic methods of submitting to the
2 Secretary a licensure application required
3 under this section and provide for elec-
4 tronic methods of receiving the applica-
5 tions.

6 “(ii) AUTHENTICATION.—In providing
7 for the electronic submission of such licen-
8 sure applications under this section, the
9 Secretary shall ensure that adequate au-
10 thentication protocols are used to allow
11 identification of the Internet pharmacy and
12 validation of the data as appropriate.

13 “(4) LIST.—

14 “(A) IN GENERAL.—The Secretary shall
15 compile, maintain, and periodically update a list
16 of licensees.

17 “(B) AVAILABILITY.—The Secretary shall
18 make the list described under subparagraph (A)
19 and information submitted by the licensee
20 under paragraph (2)(B) available to the public
21 on an Internet website and through a toll-free
22 telephone number.

23 “(5) TERMINATION OF LICENSE.—The Sec-
24 retary, upon the initiative of the Secretary, may ter-
25minate a license issued under subsection (c), after

1 notice to the Internet pharmacy and an opportunity
2 for a hearing, and if the Secretary determines that
3 an Internet pharmacy—

4 “(A) has demonstrated a pattern of non-
5 compliance with this section;

6 “(B) has made an untrue statement of ma-
7 terial fact in its license application; or

8 “(C) is in violation of any applicable Fed-
9 eral or State law relating to the dispensing of
10 a prescription drug.

11 “(6) RENEWAL EVALUATION.—

12 “(A) IN GENERAL.—Before renewing a li-
13 cense of an Internet pharmacy under this sub-
14 section pursuant to the submission of a renewal
15 application, the Secretary shall conduct an eval-
16 uation to determine whether the Internet phar-
17 macy is in compliance with this section.

18 “(B) EVALUATION.—At the discretion of
19 the Secretary and as applicable, an evaluation
20 under subparagraph (A) may include testing of
21 the Internet pharmacy website or other systems
22 through which the Internet pharmacy commu-
23 nicates with consumers, and a physical inspec-
24 tion of the records and premises of the phar-
25 macy.

1 “(7) CONTRACT FOR OPERATION OF PRO-
2 GRAM.—

3 “(A) IN GENERAL.—The Secretary may
4 award a contract under this subsection for the
5 operation of the licensing program.

6 “(B) TERM.—The duration of a contract
7 under subparagraph (A) shall not exceed 5
8 years and may be renewable.

9 “(C) PERFORMANCE REVIEW.—The Sec-
10 retary shall annually review performance under
11 a contract under subparagraph (A).

12 “(d) PROVIDERS OF INTERACTIVE COMPUTER SERV-
13 ICES OR ADVERTISING SERVICES.—A provider of inter-
14 active computer services (as defined in section 230(f) of
15 the Communications Act of 1934 (47 U.S.C. 230(f))) or
16 an advertising service provider shall be liable under this
17 section for dispensing or selling prescription drugs in vio-
18 lation of this section on account of another person’s selling
19 or dispensing of a prescription drug if the provider of the
20 service—

21 “(1) accepts advertising for a prescription drug
22 from an Internet pharmacy that is not licensed in
23 accordance with this section; or

1 “(2) accepts advertising stating that an indi-
2 vidual does not need a physician’s prescription to ob-
3 tain a prescription drug.

4 “(e) REPORTS REGARDING INTERNET-RELATED VIO-
5 LATIONS OF FEDERAL AND STATE LAWS ON DISPENSING
6 OF DRUGS.—The Secretary shall, pursuant to the submis-
7 sion of an application meeting criteria prescribed by the
8 Secretary, make an award of a grant or contract to an
9 entity with experience in developing and maintaining sys-
10 tems for the purpose of—

11 “(1) identifying Internet pharmacy websites
12 that are not licensed in accordance with this section
13 or that appear to be operating in violation of Fed-
14 eral or State laws concerning the dispensing of
15 drugs;

16 “(2) reporting such Internet pharmacy websites
17 to State medical licensing boards and State phar-
18 macy licensing boards, and to the Attorney General
19 and the Secretary, for further investigation; and

20 “(3) submitting, for each fiscal year for which
21 the award under this subsection is made, a report to
22 the Secretary describing investigations undertaken
23 with respect to violations described in paragraph
24 (1).”.

1 (b) PROHIBITED ACTS.—Section 301 of the Federal
2 Food, Drug, and Cosmetic Act (21 U.S.C. 331), as
3 amended by section 8(a) of this Act, is amended by adding
4 at the end the following:

5 “(kk) The sale of a prescription drug, or the owner-
6 ship or operation of an Internet pharmacy, in violation of
7 section 503B.

8 “(ll) The representation by advertisement, sales pres-
9 entation, direct communication (including telephone, fac-
10 simile, or electronic mail), or otherwise by an Internet
11 pharmacy, that a prescription drug may be obtained from
12 the Internet pharmacy without a prescription, in violation
13 of section 503B.

14 “(mm) The acceptance of an advertisement from an
15 Internet pharmacy by the provider of an interactive com-
16 puter service, unless the provider has on file a copy of
17 the license issued to the Internet pharmacy under section
18 503B.”.

19 (c) INJUNCTIVE PROCEEDINGS; LINKS TO ILLEGAL
20 INTERNET PHARMACIES.—Section 302 of the Federal
21 Food, Drug, and Cosmetic Act (21 U.S.C. 332) is amend-
22 ed by adding at the end the following:

23 “(c)(1) In the case of a violation of section 503B re-
24 lating to an illegal Internet pharmacy, the district courts
25 of the United States and the United States courts of the

1 territories shall have jurisdiction to order a provider of
2 an interactive computer service to remove, or disable ac-
3 cess to, an Internet website violating that section that re-
4 sides on a computer server that the provider controls or
5 operates.

6 “(2) Relief under paragraph (1)—

7 “(A) shall be available only after provision to
8 the provider of notice and an opportunity to appear;

9 “(B) shall not impose any obligation on the
10 provider to monitor its service or to affirmatively
11 seek facts indicating activity violating section 503B;
12 and

13 “(C) shall specify the provider to which the re-
14 lief applies.”.

15 (d) IMPORTATION; RETURN TO SENDER.—Section
16 801 of the Federal Food, Drug, and Cosmetic Act (21
17 U.S.C. 381), as amended by section 7(b) of this Act, is
18 amended by adding at the end the following:

19 “(q) UNLICENSED INTERNET PHARMACY.—If an
20 Internet pharmacy is not licensed by the Secretary in ac-
21 cordance with section 503B, any shipment of a prescrip-
22 tion drug from such an Internet pharmacy to an individual
23 shall be refused admission into the United States and the
24 Secretary shall return the prescription drug, other than
25 a prescription drug that is required to be destroyed, to

1 the Internet pharmacy at the expense of the Internet phar-
2 macy.

3 “(r) LICENSED INTERNET PHARMACY.—If a ship-
4 ment of a prescription drug from an Internet pharmacy
5 licensed by the Secretary in accordance with section 503B
6 to an individual is refused admission into the United
7 States, the Secretary shall—

8 “(1) return the prescription drug, other than a
9 prescription drug that is required to be destroyed, to
10 the Internet pharmacy at the expense of the Internet
11 pharmacy; and

12 “(2) provide the individual and the Internet
13 pharmacy with a written notice that informs the in-
14 dividual and the Internet pharmacy of the refusal
15 and of the reason for the refusal.”.

16 (e) REGULATIONS.—With respect to section 503B of
17 the Federal Food, Drug, and Cosmetic Act (as added by
18 subsection (a) of this section):

19 (1) Not later than one year after the date of
20 the enactment of this Act, the Secretary of Health
21 and Human Services shall promulgate interim final
22 regulations that are consistent with the Verified
23 Internet Pharmacy Sites certification program devel-
24 oped by the National Association of Boards of Phar-

1 macy to carry out the amendments made by this sec-
 2 tion.

3 (2) The requirement of licensure under such
 4 section 503B takes effect on the date determined by
 5 the Secretary of Health and Human Services, but in
 6 no event later than 90 days after the effective date
 7 of the interim final regulations under paragraph (1).

8 (3) Section 801(q) of such Act (as added by
 9 subsection (d) of this section) takes effect on the ef-
 10 fective date that applies under paragraph (2) of this
 11 subsection.

12 (4) For purposes of section 813 of such Act (as
 13 added by section 4 of this Act), an Internet phar-
 14 macy located in Canada is deemed to be licensed
 15 under such section 503B pending the effective date
 16 that applies under paragraph (2) of this subsection.

17 **SEC. 10. CHAIN OF CUSTODY OF PRESCRIPTION DRUGS;**
 18 **NETWORK FOR NOTIFICATIONS REGARDING**
 19 **COUNTERFEIT DRUGS.**

20 (a) **ELECTRONIC TRACK AND TRACE TECHNOLOGY;**
 21 **NETWORK FOR NOTIFICATIONS REGARDING COUNTER-**
 22 **FEIT DRUGS.—**

23 (1) **ELECTRONIC TRACK AND TRACE TECH-**
 24 **NOLOGY.—**Not later than December 31, 2007, the
 25 Secretary of Health and Human Services shall re-

1 quire the adoption and use of electronic track and
2 trace technology for a prescription drug at the case
3 and pallet level that will identify each sale, purchase,
4 or trade of that case or pallet (including the date of
5 transmission and the names and addresses of all
6 parties to the transaction).

7 (2) NETWORK FOR NOTIFICATIONS REGARDING
8 COUNTERFEIT DRUGS.—Section 503(e) of the Fed-
9 eral Food, Drug, and Cosmetic Act (21 U.S.C.
10 353(e)) is amended by adding at the end the fol-
11 lowing:

12 “(4) The Secretary shall—

13 “(A) establish a network for the purpose of pro-
14 viding prompt notification to health professionals
15 and the public of counterfeit drugs subject to sub-
16 section (b);

17 “(B)(i) develop and publish an Internet acces-
18 sible-reference document to facilitate the positive
19 identification by health professionals and regulatory
20 agency personnel of prescription drugs marketed in
21 the United States and Canada; and

22 “(ii) update the materials described under
23 clause (i) quarterly and when a new permitted coun-
24 try is designated by the Secretary;

1 “(C) develop and publish educational materials
2 to health professionals and consumers identify and
3 report cases of counterfeit drugs subject to sub-
4 section (b);

5 “(D) develop and publish secure business prac-
6 tice guidelines for the sale and distribution of such
7 drugs in cooperation with members of a drug supply
8 chain; and

9 “(E) in cooperation with the National Associa-
10 tion of Boards of Pharmacy, develop and publish re-
11 vised model rules for licensure of drug wholesalers
12 for adoption by the States.”.

13 (3) AUTHORIZATION OF APPROPRIATIONS.—For
14 the purpose of carrying out this subsection and the
15 amendments made by this subsection, there are au-
16 thorized to be appropriated such sums as may be
17 necessary for each fiscal year, in addition to other
18 authorizations of appropriations that are available
19 for such purpose.

20 (b) REQUIRED RECORDS.—Section 503(e) of the
21 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(e))
22 is amended by striking “(e)(1)(A)” and all that follows
23 through the end of paragraph (1) and inserting the fol-
24 lowing:

1 “(e)(1) A distributor of record that is engaged in the
2 wholesale distribution of a drug subject to subsection (b)
3 shall—

4 “(A) before each wholesale distribution of the
5 drug—

6 “(i) with respect to each wholesale dis-
7 tribution of a drug subject to subsection (b),
8 provide the person that receives the drug a
9 statement that identifies the immediately pre-
10 vious distributor of record from which the drug
11 was purchased; and

12 “(ii) with respect to a drug subject to sub-
13 section (b) that is imported to the United
14 States, provide the person that receives the
15 drug a statement (in such form and containing
16 such information as the Secretary may require)
17 identifying each prior sale, purchase, or trade of
18 the drug (including the date of transmission
19 and the names and addresses of all parties to
20 the transaction); and

21 “(B) create, maintain for 2 years, and make
22 available to the Secretary for inspection at reason-
23 able time, records that—

1 “(i) with respect to each wholesale dis-
 2 tribution of a drug subject to subsection (b),
 3 identifies—

4 “(I) the immediately previous dis-
 5 tributor of record from which the drug was
 6 purchased; and

7 “(II) the immediately subsequent dis-
 8 tributor of record to which the drug was
 9 sold or otherwise transferred; and

10 “(ii) with respect to a drug subject to sub-
 11 section (b) that is imported to the United
 12 States, identifies—

13 “(I) each previous distributor of
 14 record from which the drug was purchased
 15 or otherwise transferred; and

16 “(II) each subsequent distributor of
 17 record to which the drug was sold or other-
 18 wise transferred, to the extent feasible.”.

19 (c) DISTRIBUTORS OF RECORD.—Section 503(e) of
 20 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 21 353(e)) is amended by striking paragraph (3) and insert-
 22 ing the following:

23 “(3) For the purposes of this subsection and sub-
 24 section (d)—

25 “(A) the term ‘distributor of record’—

1 “(i) means a person that takes title to or
2 possession of a drug subject to subsection (b)
3 from manufacture to retail sale;

4 “(ii) includes a person that manufacturers,
5 processes, packs, distributes, receives, holds,
6 imports, or offers for importation a drug sub-
7 ject to subsection (b); and

8 “(iii) does not include a transporter;

9 “(B) the term ‘transporter’ means the United
10 States Postal Service, or equivalent governmental
11 service of a foreign country, or a private carrier en-
12 gaged in the business of transporting packages for
13 hire; and

14 “(C) the term ‘wholesale distribution’ means
15 the distribution of a drug subject to subsection (b)
16 to other than the consumer or patient but not in-
17 cluding an intracompany sale or distribution of a
18 drug described in subsection (c)(3)(B).”.

○